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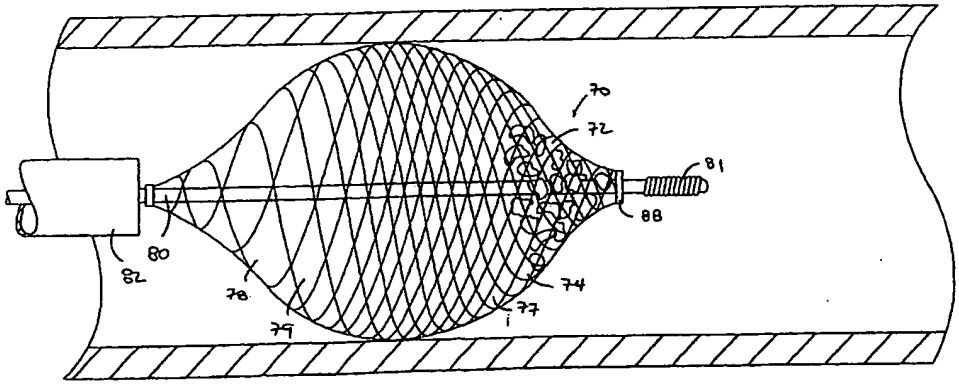
(54) Title: FILTERING DEVICES AND METHODS FOR FILTERING FLOW THROUGH A BODY STRUCTURE



(57) Abstract: An intravascular filter (30) for filtering fluid flow through a body structure has a woven or braided filter element (32). The filter mesh (32) has a first portion with openings sized to filter out unwanted material and a second portion with larger openings. The openings are sized so that the unwanted material passes through the second portion and is trapped by the first portion.

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FILTERING DEVICES AND METHODS FOR FILTERING FLOW THROUGH A BODY STRUCTURE

BACKGROUND OF THE INVENTION

The present invention is directed to methods and devices for filtering fluid flow through body structures. Such devices are used in various parts of the body, such as the vascular system, to filter out unwanted material.

Filters are used in the vascular system to remove plaque and other material which can obstruct blood vessels. Vascular filtering devices may be used during other procedures such as angioplasty, stenting, endarterectomy or atherectomy. During such interventional procedures, there is a danger of breaking plaque free from the vessel walls. Filters are used to prevent plaque and other material which may be dislodged during such interventional procedures from traveling downstream where they can obstruct or restrict blood flow.

The present invention is directed to improved methods and devices for filtering fluid flow in patients and, in particular, for filtering blood flow.

SUMMARY OF THE INVENTION

A filter device is provided for filtering flow through a body passage. The filter device has a woven or braided filter element which preferably forms a closed-mesh structure. The filter element has a first portion which has smaller openings than a second portion in the expanded position. Fluid to be filtered flows through the second portion and material is caught by the tighter mesh at the first portion. The filter element is preferably a closed mesh structure with the first portion having a concave portion which traps the unwanted material. When the filtering is complete, the filter element is collapsed to trap the filtered material inside the closed-mesh structure of the filter element.

These and other features and advantages of the invention will become apparent from the following description of the preferred embodiments, drawings and claims.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 shows a filter device in a collapsed position for introduction into a body structure.

Figure 2 shows the filter device of Figure 1 in an expanded position with material caught within the filter device.

Figure 3 shows another filter device in a collapsed position for introduction into a body structure.

Figure 4 shows the filter device of Figure 3 in the expanded position with material caught within the filter device.

Figure 5 shows still another filter device in the collapsed position for introduction into a body structure.

Figure 6 shows the filter device of Figure 5 in the expanded position with material caught within the filter device.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

Referring to Figs. 1 and 2, a filter device 30 for filtering fluid flow through a body passage, such as a blood vessel, is shown. The filter device 30 is advanced through the body passage in the collapsed position and expanded at the desired location to filter fluid flow through the body passage. For example, the filter device 30 may be used to filter out unwanted material in blood vessels such as the carotid arteries, saphenous vein grafts, superior and inferior vena cava, and renal arteries. The filter device 30 may also be used in any other part of the body such as the lymphatic and urinary systems.

The filter device 30 has a filter element 32 which expands to engage the body passage as shown in Fig. 2. The filter element 32 is preferably braided or woven but may also be formed with integrally formed elements. The filter element 32 is preferably naturally biased to the expanded position of Fig. 2 but may also be mechanically actuated. The filter element 32 is contained in a sheath 34 which holds the filter element 32 in the collapsed position as shown Fig. 1. The filter element 32

is attached to a shaft 35 which is manipulated to advance and withdraw the filter element 32 relative to the sheath 34.

The filter element 32 has a first portion 36 which filters out the unwanted material. The first portion 36 has smaller openings 37 than openings 39 in the second portion 38 so that the unwanted material in the fluid flow is captured by the first portion 36 and not the second portion 38. The filter element 32 preferably forms a closed-mesh structure with the first portion 36 having a concave surface 40 which receives the unwanted material. The size of the openings 37 in the first portion 36 is selected to remove the unwanted material based upon the particular application. Although the second portion 38 does not filter out the unwanted material, the second portion 38 helps to provide uniform expansion and collapse of the first portion since filaments 44 of the first portion 36 are preferably continuous with filaments 44 of the second portion. The second portion 38 also helps to trap the unwanted material when the filter element 32 is collapsed and withdrawn into the sheath 34.

The first portion 36 preferably has a higher "pic" or braid density than the second portion 38 which results in the smaller openings 37. Alternatively, the first portion 36 may be coated to decrease the opening size of the first portion 36. Although the first portion 36 is positioned distal to the second portion 38 to filter fluid flowing in the direction of arrow 42, the first and second portions 36, 38 may be switched for filtering fluid flow in the opposite direction.

The first and second portions 36, 38 of the filter device 30 are preferably formed with 8-64 filaments 44, preferably about 24 filaments 44, which are braided or woven. The number of filaments 44 does, of course, depend upon the particular application and more or fewer filaments 44 may be used. Furthermore, the filter element 32 may be formed from integrally formed filaments 44 as mentioned above. The filaments 44 are preferably made of a superelastic material, such as nitinol, but may also be made of any other suitable material. The material may be annealed or formed to preferentially expand to the desired deployed shape. The filter device 30 is designed to automatically expand to the position of Fig. 2 but may also be a heat-activated structure which utilizes shape memory characteristics to return to the expanded shape of Fig. 2.

The shaft 35 is preferably made of stainless steel although any suitable material may be used. The shaft 35 may have a lumen 43 to receive other devices or

for delivery or withdrawal of fluids. The shaft 35 preferably has an outer diameter of about 0.010 to 0.020 inch when used in the cerebral vasculature but may have any size depending upon the particular application.

Use of the filter device 30 is now described. The filter element 32 is advanced to the desired location preferably through another catheter such as a guiding catheter (not shown). The sheath 34 is then retracted so that the filter element 32 is exposed and expands to the position of Fig. 2. The filter element 32 is maintained in this position to filter out unwanted material for a period of time so that unwanted material is captured by the filter element 32. The filter element 32 is then withdrawn into the sheath 34 to collapse the filter element 32 thereby trapping the unwanted material in the filter element 32.

Referring to Figs. 3 and 4, another filter device 70 is shown for filtering flow through a body structure. The filter device 70 has many of the same features of the filter device 30 and is used in substantially the same manner as the filter device 30 described above. The filter device 70 has a filter element 72 movable from the collapsed position of Fig. 3 to the expanded position of Fig. 4. The filter element 72 is similar to the filter element 32 in that the filter element 72 has a first portion 74 with smaller openings 77 than openings 79 in a second portion 78. The openings 76 in the first portion are sized to remove unwanted material in the fluid flow through the body passage while the openings 79 in the second portion 78 are sized larger than the openings 77 in the first portion to permit the material to pass therethrough. The filter element 72 is held in the collapsed position by a delivery catheter 82 which has an inner diameter of 0.018-0.026 inch.

The filter element 72 is mounted to a shaft 80 which preferably has a 0.006-0.010 inch diameter when used in small vessels although any suitable size may be used depending upon the particular application. A coil 81, preferably a stacked platinum coil, is positioned at the distal end of the shaft 80 to provide a soft, atraumatic end. The filter element 72 is attached to the shaft 80 at one end 86 and to a collar 88 which slides along the shaft 80 at the other end 88. The collar 88 moves along the shaft 80 when the filter element 72 moves between the collapsed and expanded positions. The collar 88 may also be positioned at the other end 88 of the filter element 72 without departing from the scope of the invention. The filter device

70 is used in the same manner as the filter devices described above and the discussion above is incorporated here.

The filter device 70 is advanced to the desired filtering location and the filter element 72 is expanded by withdrawing the delivery catheter 82 to permit the filter element 72 to expand. Unwanted material passes through the second portion 78 and is trapped by the first portion 74 of the filter element 72. The filter device 70 is then collapsed by moving the delivery catheter 82 over the filter element 72 and the filter device 70 is removed from the body.

Yet another filter device 90 is shown in Figs. 5-6. The filter device 90 has a filter element 92 which acts in the same manner as the filters described above in that openings 94 in a first portion 93 are smaller than openings 96 in a second portion 95. The filter device 90 has a pull wire 100 attached to the distal end of the filter element 92. The filter element 98 is naturally biased toward the collapsed position of Fig. 5 and is expanded by pulling the pull wire 100. A proximal end 102 of the filter element 92 is attached to a sheath 104 through which the pull wire 100 extends. When the filter element 92 is at the desired location for filtering fluid flow, the pull wire 100 is pulled relative to the sheath 104 to move the filter element to the expanded position of Fig. 6.

While the above is a complete description of the preferred embodiments of the invention, various alternatives, substitutions and modifications may be made without departing from the scope thereof, which is defined by the following claims. For example, the filter device may take on other shapes and sizes, the filter may be formed with an integrally formed mesh, and the filter device may be used in any part of the body other than the vascular system

WHAT IS CLAIMED IS:

1. A filter device for filtering flow through a body lumen, comprising:

a shaft; and

a filter element coupled to the shaft, the filter element being movable from a collapsed position to an expanded position, the filter element having a first portion and a second portion, the first portion having first openings sized to remove unwanted material from the body lumen and the second portion having second openings larger than the first openings when in the expanded position.

2. The filter device of claim 1, wherein:

the filter element is formed by interlocking filaments, the filaments having a higher density at the first portion than at the second portion.

3. The filter device of claim 1, wherein:

the filter element forms a closed mesh structure.

4. The filter device of claim 1, wherein:

the first portion forms a concave surface which traps the unwanted material.

5. The filter device of claim 1, wherein:

the filter element is naturally biased toward the expanded position.

6. The filter device of claim 1, further comprising:

a sheath;

the filter element being contained within the sheath when in the collapsed position and being outside the sheath when in the expanded position.

7. The filter device of claim 6, wherein:

the filter device is mounted to a shaft at one end, the filter device being slidably coupled to the shaft at the other end.

8. The filter device of claim 1, further comprising:

a sheath; and

a shaft;

wherein the filter device is attached to the sheath at one end and to the shaft at the other end, the shaft being moved relative to the sheath to move the filter element to the expanded position.

9. A method of filtering unwanted material in a body lumen, comprising the steps of:

providing a filter element movable from a collapsed position to an expanded position, the filter element having a first portion and a second portion, the first portion having smaller openings than the second portion when in the expanded position;

introducing the filter element into a body lumen in the collapsed position;

expanding the filter element to the expanded position;

flowing fluid through the filter element to filter out unwanted material, the unwanted material passing through the second portion and being trapped by the first portion; and

collapsing the filter element after the flowing step to trap the unwanted material in the filter element.

10. The method of claim 9, wherein:

the providing step is carried out with the filter element forming a closed-mesh structure, the first portion forming a concave structure which receives the unwanted material.

11. The method of claim 9, wherein:

the providing step is carried out with the filter being held in the collapsed position and being naturally biased toward the expanded position.

12. The method of claim 6, wherein:

the introducing step is carried out with the filter element being positioned within a sheath; and

the expanded step is carried out by extending the filter element from the sheath to permit the filter element to expand.

13. The method of claim 9, wherein:

the providing step is carried out with the filter element attached to a shaft at one end and slidably coupled to the shaft at the other end.

14. The method of claim 9, wherein:

the providing step is carried out with the filter element being formed by interlocking filaments, the filaments having a higher density at the first portion than at the second portion when in the expanded position.

15. The method of claim 9, wherein:

the providing step is carried out with the filter element forming a closed mesh structure.

16. The method of claim 9, wherein:

the providing step is carried out with the filter element being connected to a shaft at one end and to a sheath at the other end, the shaft passing through the sheath; and

the expanding step is carried out by moving the shaft relative to the sheath.

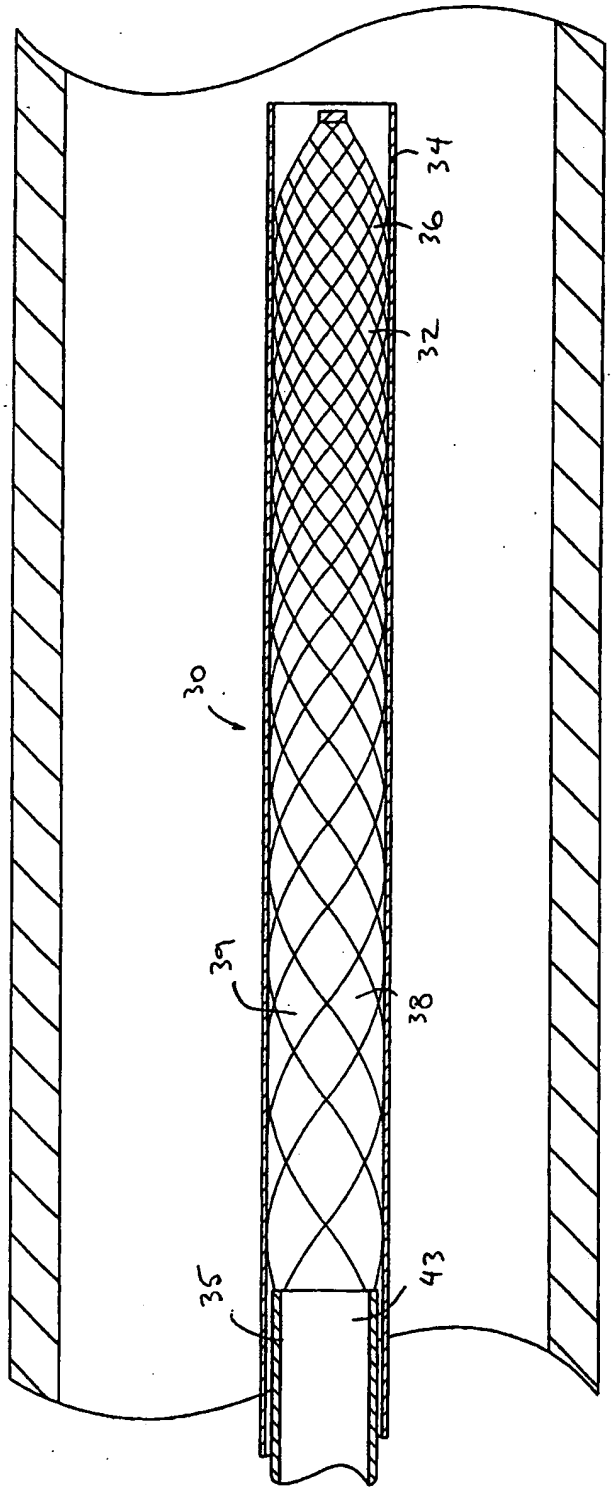

FIG. 1

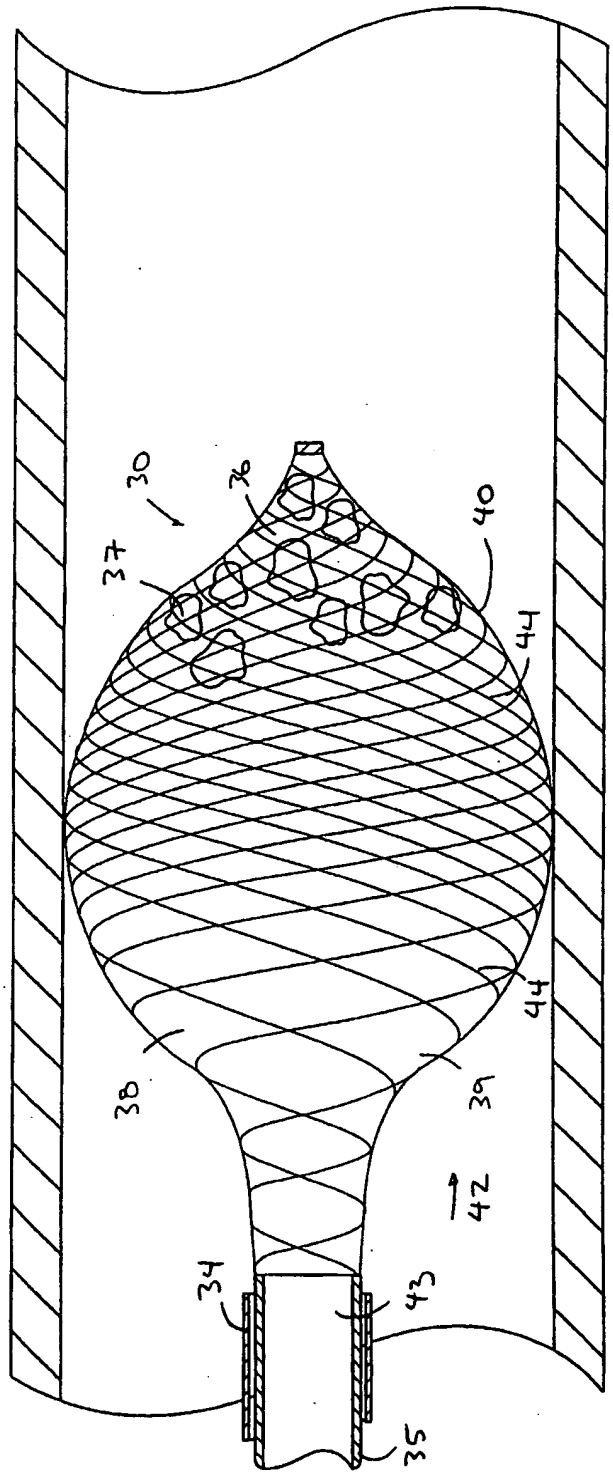

FIG. 2

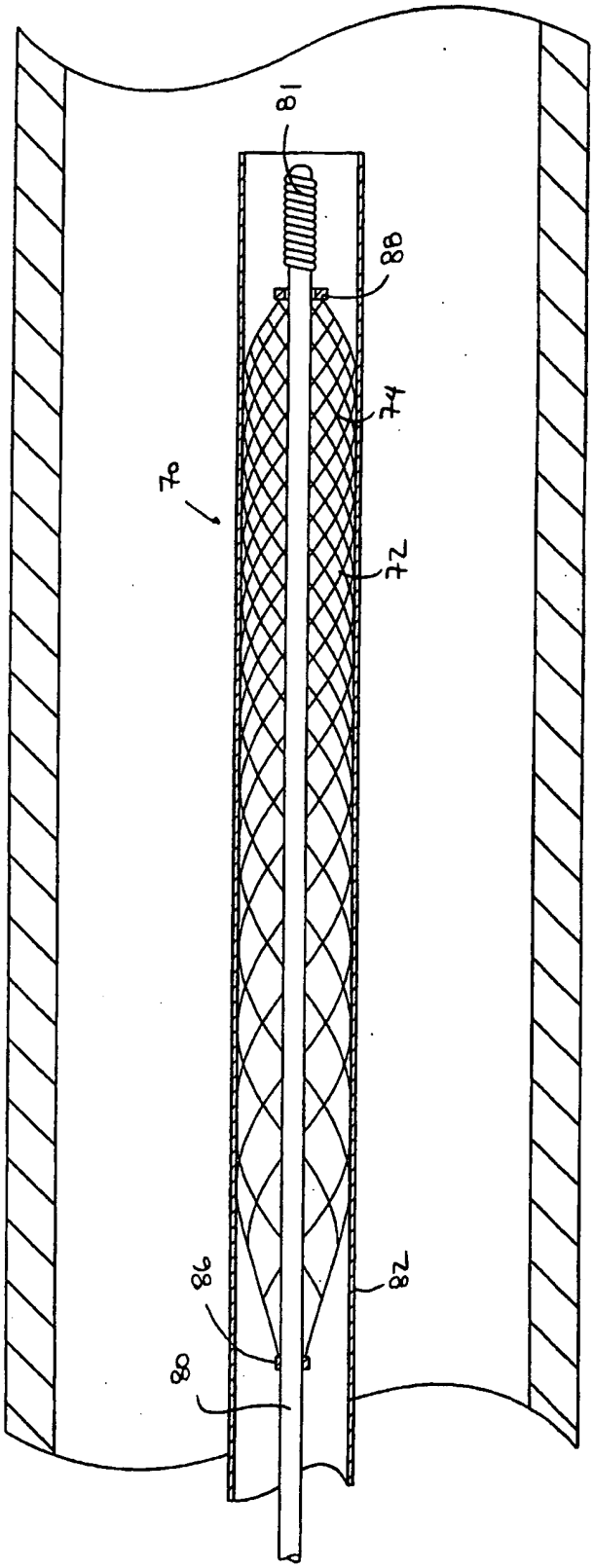

FIG. 3

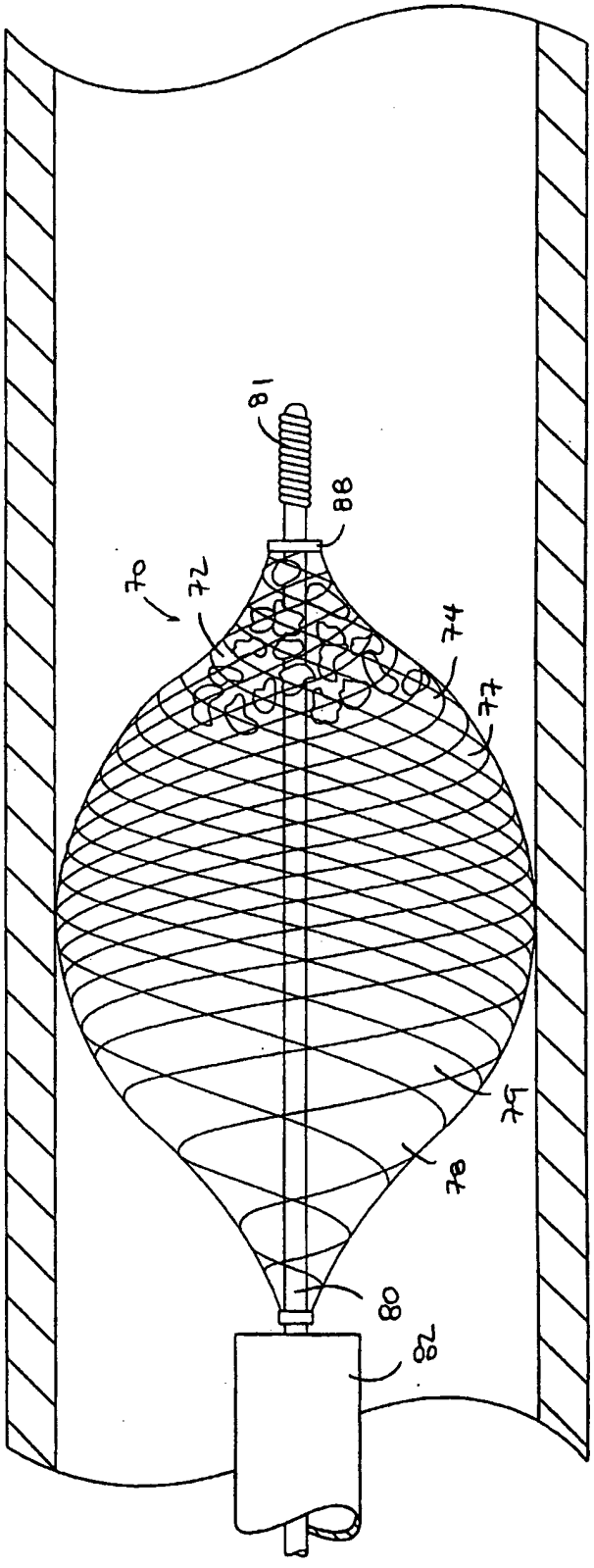

FIG. 4

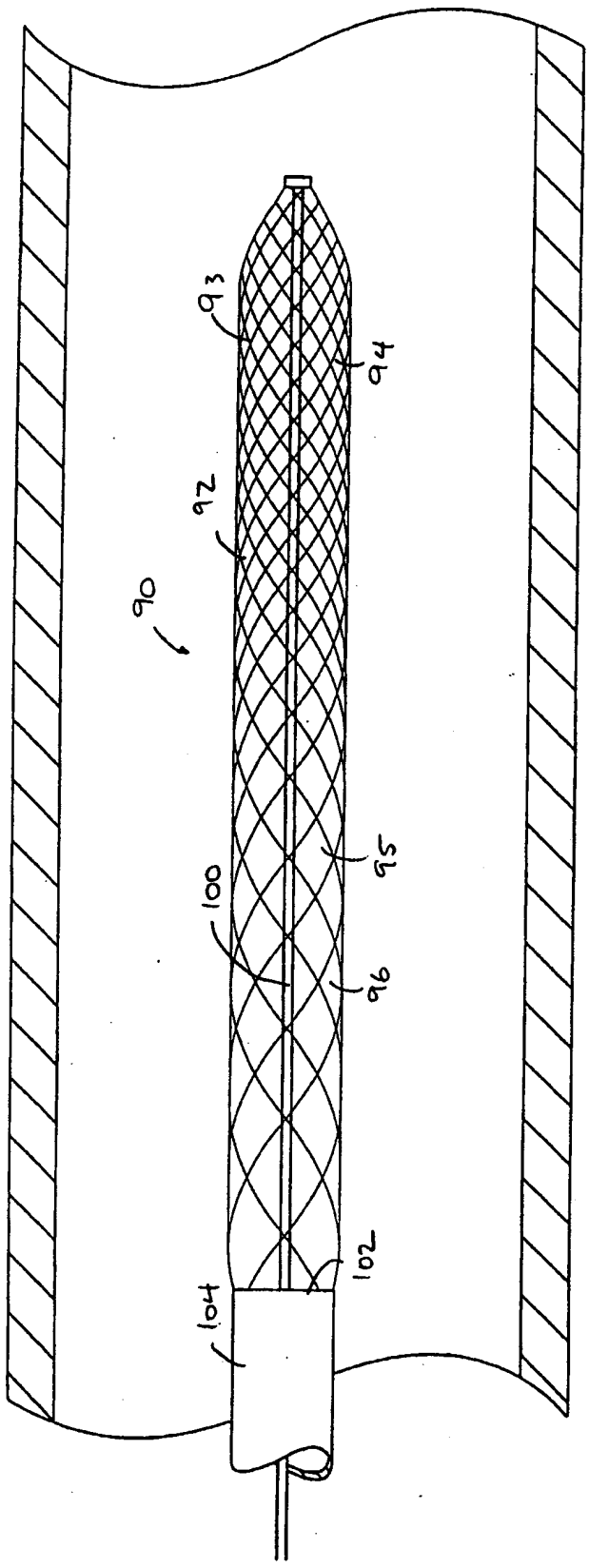

FIG. 5

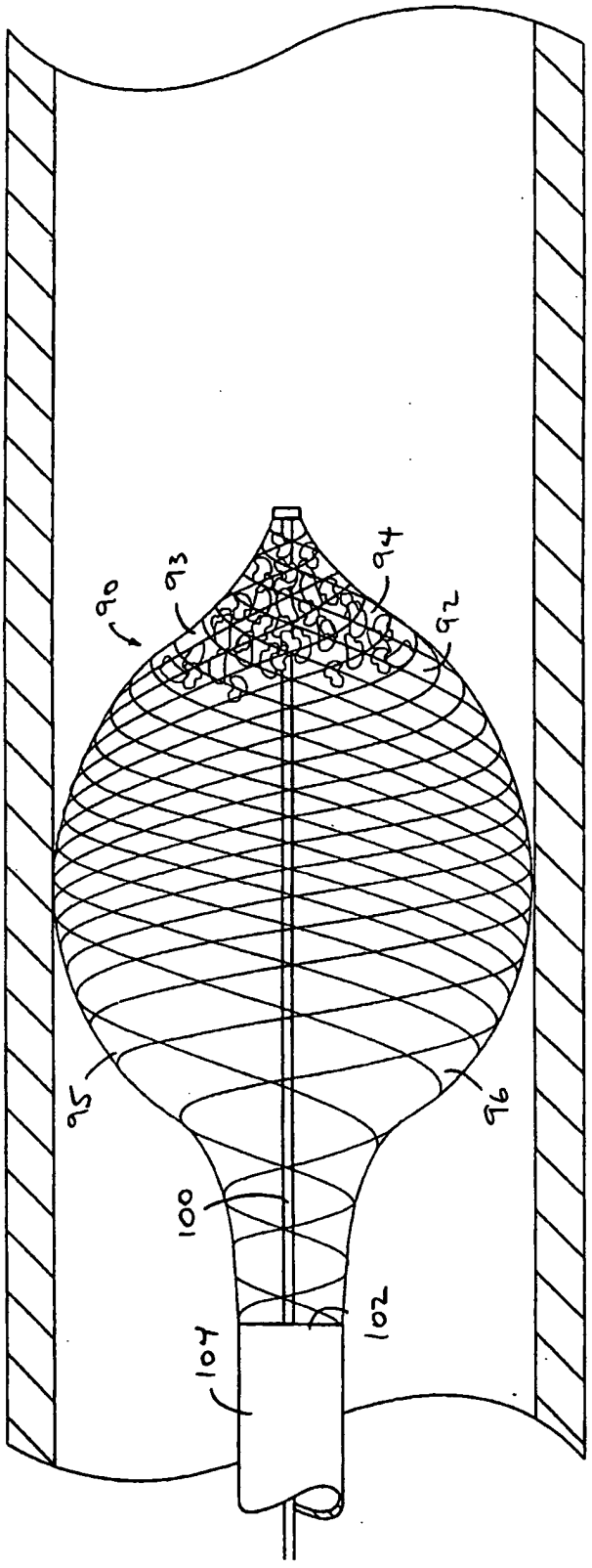

FIG. 6

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US01/04856

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) :A61M 29/00
US CL :604/104

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 604/104, 101, 96, 284, 507, 508, 509, 510, 104; 606/192-194, 200; 600/159

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

NONE

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

NONE

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A, E	US 6,224,620 B1 (MAAHS) 01 May 2001, see entire patent.	1-16
A, E	US 6,231,544 B1 (TSUGITA ET AL.) 15 May 2001, see entire patent.	1-16
A, E	US 6,221,006 B1 (DUBRUL ET AL.) 24 April 2001, see entire patent.	1-16

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